Note: Still open, last updated 7/12/01.

October 26, 1998

OFFICE OF RESEARCH AND DEVELOPMENT
HEALTH SERVICES RESEARCH AND DEVELOPMENT SERVICE (HSR&D)

PROGRAM ANNOUNCEMENT

VA QUERI
Quality Enhancement Research Initiative

Investigator-Initiated Research on Common Issues in Implementation of Clinical Practice Guidelines

1. Purpose. The Veterans Health Administration (VHA) is focusing major resources and energy to improve the quality of the health care it provides and to create improvements that are measurable, rapid and sustainable. With the inauguration of the Quality Enhancement Research Initiative (QUERI) in early 1998, special emphasis has been placed on improving the quality of care in ten clinical areas that are prevalent in VA: chronic heart failure, ischemic heart disease, diabetes, prostate disease, stroke, substance abuse, mental health (depression and schizophrenia), spinal cord injuries, HIV/AIDS, and cancer. For each of these areas, QUERI will identify gaps in science, practice, and information systems, and will develop and evaluate methods for translating evidence of clinical effectiveness into practice. Additional information about QUERI is available on the VA web page at http://www.va.gov/resdev.

One promising approach to improving health care quality is the use of clinical practice guidelines. When based on careful and up-to-date reviews of the scientific evidence, clinical practice guidelines have potential to foster clinical decisions that improve patient outcomes and promote rational use of health care resources. A 1996 directive established that "It is VHA policy that VA facilities will use nationally developed clinical practice guidelines." VHA's Office of Patient Care Services and Office of Performance and Quality have joint responsibility for developing guidelines within VA and for authorizing the adoption of guidelines developed outside of VA. Implementation of these guidelines is the responsibility of all network directors.

2. Synopsis. This Program Announcement invites eligible VA investigators (see paragraph 6a) to propose Investigator-Initiated Research (IIR) projects that will identify effective and cost effective strategies for implementing clinical guidelines in VA health care facilities. Projects may request up to four years and total cost of up to $750,000; however, HSR&D is especially interested in projects that can demonstrate results in a shorter timeframe. For the initial round of review, a brief planning letter (see Attachment A) must

be received by December 10, 1998, and full proposals must be received by February 5, 1999. The first proposal review opportunity will be March, 1999, with the earliest possible funding date of April 1999. Thereafter, projects will require a Letter of Intent consistent with regular IIR policy, and proposal due dates are May 1 and November 1, until further notice.

This solicitation emphasizes *generalizable, useful* findings. Projects are to address common, generic, or cross-cutting issues in guideline implementation and strategies that may be replicated (or barriers that may be reduced) *system-wide* or across all VA facilities of a particular type (e.g., nursing homes, outpatient clinics). Either of the following approaches may be taken:

(1) focus on *common implementation issue(s)* for *two or more different guidelines*; or

(2) focus on the implementation of a *single set of guidelines* (e.g., guidelines for schizophrenia or congestive heart failure) *in different situations* (e.g., different health care settings, for different patient or provider groups).

Note: All projects are to select guidelines for one or more of the conditions that are part of QUERI (see paragraph 1). The guideline(s) to be studied need to be identified and a clear rationale for the selection must be provided. Also note, as part of QUERI, HSR&D will issue separate solicitations for research on guideline implementation issues that are *unique* to certain QUERI conditions. All solicitations will be posted on VA's web page, at http://www.va.gov/resdev/hsr-sols.htm.

It is well recognized that the *availability* of guidelines does not ensure their implementation. Barriers to guideline implementation include provider issues (knowledge, attitudes, and behavior) and system issues (e.g., resources, culture, patient population, etc.). Research proposed in response to this announcement may address strategies to identify and address any of these barriers. See section 4, below, for specific examples of research issues.

3. Guidelines Appropriate for Study. Research proposed in response to this solicitation concerns *available* clinical practice guidelines that are evidence-based *and* developed by VA, the Agency for Health Care Policy and Research (AHCPR), or other national or international research and professional groups. VHA policy defines clinical practice guidelines as "recommendations for the performance or exclusion of specific procedures or services derived through a rigorous methodological approach …" **NOTE:** Projects that focus on guidelines based on expert opinion or consensus statements and guidelines developed by individuals or individual institutions, are not responsive to this announcement. Further, these funds are not available for projects that propose to develop new practice guidelines or to evaluate the validity of existing guidelines.

4. Sample Research Issues. Starting with a clinical practice guideline(s) that meets the above criteria, studies are to focus on alternative strategies for, or facilitators and barriers to, effective guideline implementation. Examples of suitable research questions include, but are not limited to the following:

- What strategy (e.g., incentives, sanctions, training, reminders, feedback, quality

assurance checks, administrative requirements, use of "champions" and opinion leaders, etc.) contributes most to the acceptance, adoption, accuracy and/or consistency in guideline use in different types of VA health care settings?

- What strategy is the most cost effective? Is there a *single* best strategy for an array of clinical conditions and/or settings?

- How can VA patients be effectively involved in guideline implementation?

- What costs are associated with various strategies to implement guidelines, in terms of additional personnel or administrative mechanisms required? Are these costs justified by gains in quality of care?

- What are the most effective strategies for communicating information about updates or revisions to guidelines that have already been implemented?

- In the implementation of different types of guidelines, what group (primary care physicians, specialists, non-physician providers, patients) is the most effective and cost-effective target, and what are the ideal roles and interactions of these groups?

- Optimal guideline implementation may not call for 100 percent compliance. What are appropriate and achievable measures and standards for evaluating the extent and adequacy of guideline implementation?

- What generic or condition-specific patient outcomes should be used to set goals for successful guideline implementation? What is the best way to integrate these measures into guideline implementation?

- From a health systems and managerial perspective, what are the appropriate criteria to determine whether guidelines have been implemented at a given institution? Should there be a uniform set of criteria applicable to all institutions? Should improvement in risk-adjusted outcomes be required for successful implementation?

5. Research Methods. All HSR&D studies are expected to use research designs and methods that maximize the validity, reliability, generalizability, and usefulness of findings. While the research needs to be grounded in the realities of VA practice and address real world information needs, it also needs to have a clear theoretical framework, demonstrate familiarity with the pertinent literature, and employ a data collection and analysis strategy that will yield valid conclusions. The multidisciplinary nature of health services research needs to be evident in the formulation of the research questions, and the methodological approach may draw from any, or several, discipline(s). Study teams should generally include individuals with experience and expertise in clinical and non-clinical fields, including pertinent social scientists and research methodologists. The research needs to be designed to maximize the eventual application of findings and conclusions.

Studies responsive to this solicitation are expected to meet the above general criteria. They should add new knowledge based on an appropriate conceptual framework and appropriate research design and methods, including adequate controls and statistical power. Studies should be systematic and prospective, and they should emphasize cross-

cutting issues. Applicants are advised to pay particular attention to conceptual and methodological issues that make research in guideline implementation particularly challenging.

6. Application Process.

a. Eligibility. Investigators who hold a VA appointment of at least 5/8 time are eligible to apply for research support. Co-investigators, consultants, and support staff may be non-VA employees. Refer questions about eligibility to Robert Small at 202/273-8256 or robert.small@mail.va.gov .

b. Planning Letter. A planning letter is the first step in preparing a proposal responsive to this announcement. It will be used only for administrative purposes (for format, see attachment A). The usual Letter of Intent (LOI) process required for HSR&D IIR projects, whereby a detailed description of the project must be approved prior to submitting a full proposal, **does not apply** to the initial round of review for this solicitation. Planning letters are due at the address listed in paragraph 10 ("Inquiries"), by the close of business on December 10, 1998. Facsimile and electronic mail copies will be accepted; address these to John Francis, HSR&D Service, at FAX number 202/273-9007 or john.francis@mail.va.gov.

c. Proposal Preparation and Submission. For detailed instructions regarding preparation and submission of a full proposal, and general review criteria, applicants should refer to HSR&D's "Instructions for Preparing Investigator-Initiated Research Proposals" (available at all VA research offices and on the VA research home page at http://www.va.gov/resdev).

d. Review Schedule. Proposals received by February 5, 1999 will be reviewed at the Scientific Review and Evaluation Board subcommittee meeting in March 1999. Subsequently, and until further notice, proposals responsive to this announcement, based on an approved LOI, will be reviewed at regularly scheduled meetings of the Board, along with other IIR projects. Proposals received by May 1 are reviewed in June; proposals received by Nov. 1 are reviewed in January.

7. Review Criteria. IIR review is rigorous and standards very high; both scientific merit and expected contribution to improving VA health services are considered. Any design and any method(s) consistent with paragraph 5 are acceptable. Investigators are expected to develop and describe their research plan completely and in detail. Proposals recommended for approval will be considered for funding.

In addition to the regular IIR review criteria, proposals submitted in response to this announcement are expected to meet the following special criteria:

a. Guideline(s) to be studied must meet the criteria specified in paragraph 3.

b. The focus of the research must be on the *implementation* of guidelines, *not on evaluating* any guidelines *per se*, and *not on developing* new guidelines.

c. "Implementation" is to be operationalized in terms of observed changes in practice and, when possible, changes in patient and system outcomes (cost, quality of care,

average length of stay, policy or procedure changes, practice variations), i.e., not mere dissemination of, or pronouncements about, guidelines. The study design must permit attribution of the observed outcomes to guideline adherence.

d. All projects are expected to contribute practical, generalizable information for optimizing the use of clinical practice guidelines in VHA.

8. Funding. The maximum time and total budget for projects submitted in response to this announcement is four years and $750,000. **Note:** For projects that require more than two years, investigators are strongly encouraged to identify major milestones or project components for which interim results can be reported and published. All applicants are reminded to adhere to R&D guidelines regarding allowable use of research funds for specific items. HSR&D expects to fund the first projects in the fourth quarter of 1999.

9. Coordination with QUERI and Ongoing HSR&D Research. HSR&D is currently funding a set of projects related to guideline implementation (see *Activities Receiving Funding,* 1997 and MDRC's *Clinical Practice Guidelines* Primer, available in November 1998). In developing research projects responsive to this announcement, investigators should consider ways to build on that work. Also, for funded projects related to QUERI, principal investigators will be expected to submit regular annual progress reports and requested updates to the Director, HSR&D, who will provide these to the appropriate QUERI Coordinating Center, through the Associate Director for QUERI.

10. Inquiries. For further information regarding this solicitation, contact Claire Maklan, MPH, PhD, Chief of Scientific Development, HSR&D, at claire.maklan@mail.va.gov. For information about procedures and review, including eligibility for support, contact Robert Small, at (202-273-8256 or robert.small@mail.va.gov).

John R. Feussner, M.D.
Chief Research and Development Officer

REFERENCES

Agency for Health Care Policy and Research, National Guideline Clearinghouse Website: www.guideline.gov

American Hospital Association, Division of Quality Resources, CPG Strategies: Putting Guidelines into Practice, Chicago: AHA, Sept.1992.

Anderson, G., "Implementing practice guidelines," Canadian Medical Association Journal, 148(5), 753-755, 1993.

Brown, J.B., Shye, D., and McFarland, B., "The Paradox of Guideline Implementation: How AHCPR's Depression Guideline Was Adapted at Kaiser Permanente Northwest Region," J Qual Improvement, March 1996, 5-21.

Department of Veterans Affairs, Health Services Research and Development Service, Activities Receiving Funding in Fiscal Year 1997, HSR&D Document No. 39-32-009, April 1998.

Eagle K.A., Mulley A.G., Skates S.J., et al. Length of stay in the intensive care unit: Effects of practice guidelines and feedback. JAMA 1990; 264:992-7.

Grimshaw J.M., and Russell I.T., Effect of clinical guidelines on medical practice: A systematic review of rigorous evaluations. Lancet 1993; 342(8883):1317-22.

Health Services Research and Development Service, Management Decision and Research Center, in collaboration with Association for Health Services Research, Clinical Practice Guidelines: Primer, (expected publication Nov. 1998)

Institute of Medicine, Field, M.J., and Lohr, K.N. (eds.), Guidelines for Clinical Practice: From Development to Use. Washington, DC: National Academy Press, 1992.

Karuza, J., Calkins, E., Feather, J., Hershey, C.O., Katz, L., and Majeroni, B., Enhancing physician adoption of practice guidelines. Arch Intern Med 1995, 155:625-32.

Kizer, K.W., Prescription for Change: The Guiding Principles and Strategic Objectives Underlying the Transformation of the Veterans Healthcare System. Department of Veterans Affairs. March 1996, p. 57.

Lomas, J., Enkin, M., Anderson, G.M., Hannah, W,J., Vayda, E., and Singer, J., Opinion leaders vs. audit and feedback to implement practice guidelines. JAMA 1991; 265:2202-7.

Mittman, B.S., Tonesk, X., and Jacobson, P.D., "Implementing clinical practice guidelines: Social influence strategies and practitioner behavior change," Quality Review Bulletin, 413-422, Dec. 1992.

Report of the U.S. Preventive Services Task Force, Guide to Clinical Preventive Services,

2nd edition, Baltimore: Williams & Wilkins, 1996.

VHA Directive 96-053, ”Roles and definitions for clinical practice guidelines and clinical pathways" (August 29, 1996).

ATTACHMENT A

FORMAT FOR HSR&D PLANNING LETTERS FOR PROJECTS RESPONDING TO

"COMMON ISSUES IN IMPLEMENTATION OF CLINICAL PRACTICE GUIDELINES"

Provide a one-page letter addressed to the HSR&D Review Program Manager (124F), including the following information:

1. Principal Investigator's name, affiliation, address, phone number, e-mail, and FAX number.

2. Name and affiliation of co-Principal Investigator, if applicable, and other key project participants.

3. Title and date of the solicitation to which you are responding, i.e., "Guideline Implementation", Oct. 1998.

4. Proposal title.

5. Specific focus of the proposed study.

6. Major methods to be used and type(s) of analyses to be performed.

7. (Optional) Two or more scientists who are qualified to review the proposal; include name, degree, title, academic affiliation, complete address, telephone number, and e-mail address.

8. Signature of the ACOS for R&D.